

## **REMARKS**

Applicants submit this response to the Office Action mailed August 9, 2006. Claims 12-17 and 21-23 are pending pursuant to a Restriction Requirement. Claims 12-14 and 21-23 were objected to because they encompass a non-elected invention, the polypeptide of SEQ ID NO:4. These claims are amended accordingly, and no new matter is added.

Claims 12, 13, 15-17 and 22 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The claims are drawn to polypeptides having at least 95% sequence identity with the protein of SEQ ID NO:2, or polypeptide of SEQ ID NO:2 comprising at least one conservative amino acid substitution, or an epitope bearing portion of a polypeptide comprising the amino acid sequence of SEQ ID NO:2 which comprises about 5 to 50 or 10 to 20 contiguous amino acids, or a complex comprising a fragment of the amino acid sequence of SEQ ID NO:2. According to the Examiner, the claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature.

The Examiner cited Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1117, for stating that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The Examiner also cited Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993), Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, and Fiddes v. Baird, 30 USPQ2d 1481 at 1483. The Examiner concluded that only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO:2, but not the full breadth of the claim, meets the written description provision of 35 U.S.C. § 112, first paragraph. Without acquiescing to the ground of rejection, applicants respectfully request withdrawal of the rejection in view of the amendment of claims 12 and 13 to add a biological function. Regarding claims 15 and 16 (claim 17 having being cancelled as discussed below), the term "epitope" is well-recognized in the art as conveying an

immunological function, for example as described in the specification at page 25, lines 2-10. Regarding claim 22, the claim has been amended without prejudice or disclaimer to recite a polypeptide of any of claims 12-14.

Claim 23 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 23 encompasses a pharmaceutical composition comprising the polypeptide of SEQ ID NO:2. According to the Examiner, the claims encompass a "pharmaceutical use" for the compositions, which allegedly has not been demonstrated. The Examiner stated that deletion of the word "pharmaceutical" in the claims would obviate the rejection. Without acquiescing to the ground of rejection, claim 23 has been amended accordingly.

Claims 13 and 15-17 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 is allegedly indefinite because of the term "except for at least one conservative amino acid substitution," as it is interpreted by the Examiner to encompass a protein in which the majority of amino acid residues could be substituted by a conservative amino acid, which would result in a completely different protein. Claim 13 has been amended herein, and applicants submit that this rejection may be withdrawn.

Claims 15-17 allegedly are indefinite because claim 15 recites, "An epitope-bearing portion of a polypeptide comprising consisting of SEQ ID NO: 2." Claim 15 has been amended herein.

Claims 15-17 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Dunwoodie et al., Development 124:3065-3076, 1997. According to the Examiner, claims 15-17 encompass an epitope-bearing portion of a polypeptide comprising or consisting of SEQ ID NO:2, wherein the epitope-bearing portion comprises about 5 to about 50 or about 10 to about 50 contiguous amino acids. According to the Examiner, the protein of Dunwoodie contains stretches of amino acids that are identical to those of SEQ ID NO:2, such as a 48 contiguous amino acid stretch

rejection, applicants submit that the rejection may be withdrawn in view of the amendment to claims 15 and 16, and the cancellation of claim 17.

The Examiner indicated that the full length sequence of SEQ ID NO:2 is free of the prior art. Claims 14 and 21 were objected to for reciting non-elected subject matter, and these claims have been amended herein. In view of the amendment to these claims, and the arguments and amendments in reference to the rejected claims, applicants submit that all the objections and rejections may be withdrawn.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If fees are believed necessary, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 04-0258. If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

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